NC Medicaid and NC Health Choice
Pharmacy Prior Approval Request for
Viekira: Initial PA Form

Beneficiary Information

1. Beneficiary Last Name: _____ 2. First Name: _____
3. Beneficiary ID #: _____ 4. Beneficiary Date of Birth: _____ 5. Beneficiary Gender: ____

Prescriber Information

6. Prescribing Provider NPI #: _____
7. Requester Contact Information - Name: _____ Phone #: _____ Ext._____

Drug Information

8. Drug Name: _____ 9. Strength: _____ 10. Quantity Per 30 Days: 112
11. Length of Therapy (in days): ☒ 8 weeks **(only 8 weeks can be approved with this form. Must use continuation form to request additional weeks of therapy).**

Clinical Information

Total Length of Therapy (Check ONE):
☐ **12 weeks** = Genotype 1a, without cirrhosis, or genotype 1b, with cirrhosis
☐ **24 weeks =** Genotype 1a, with compensated cirrhosis

1. Is the beneficiary is 18 years of age or older with a diagnosis of chronic hepatitis C (CHC) infection with confirmed genotype 1 b without cirrhosis or with compensated cirrhosis or confirmed genotype 1a without cirrhosis or with compensated cirrhosis in combination with ribavirin? ☐ **Yes** ☐ **No**
   Genotype is: _____ **Fibrosis stage is:** _____
2. For all treatment courses except genotype 1b (without cirrhosis), will treatment include the use of ribavirin?
   ☐ **Yes** ☐ **No**
3. Have medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype been submitted?
   ☐ **Yes** ☐ **No** ****Lab test results MUST be attached to the PA to be approved.****
4. Which of the following are included with the submitted medical records to document the staging of liver disease:
   ☐ Metavir scores ☐ FibroSURE score ☐ IASL scores
   ☐ Batts-Ludwig scores ☐ Fibroscan score ☐ Ishak scores
   ☐ APRI score Radiological imaging consistent with cirrhosis
   ☐ Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician
5. Does the beneficiary have a documented quantitative HCV RNA at baseline that was tested within the past 6 months (medical documentation required)? ☐ **Yes** ☐ **No HCV RNA (IU/ml):** _____ and/or **log10 value:** _____
6. Has the beneficiary agreed to toxicology and/or alcohol screenings as needed? ☐ **Yes** ☐**No**
7. As the provider, are you reasonably certain that treatment will improve the beneficiary's overall health status?
   ☐ **Yes** ☐**No**
8. Do you attest that the beneficiary has been evaluated for readiness for treatment and the beneficiary agrees to be compliant with therapy, follow-up appointments and labs? ☐ **Yes** ☐ **No**
9. Has the provider assessed for laboratory and clinical evidence of hepatic decompensation? ☐ **Yes** ☐ **No**
10. Does the beneficiary have cirrhosis? ☐ **Yes** ☐ **No** If answer is yes, please answer the following:
    10a. Is the beneficiary being monitored for clinical signs and symptoms of hepatic decompensation (such as ascites, hepatic encephalopathy, variceal hemorrhage)? ☐ **Yes** ☐ **No**

10b. Has the beneficiary received hepatic laboratory testing including direct bilirubin levels at baseline and during the first four weeks of starting treatment and as clinically indicated? ☐ **Yes** ☐ **No**

11. Is Viekira Pak being used in combination with other protease inhibitors used to treat CHC (i.e. boceprevir, simeprevir, or telaprevir) or in combination with another nucleotide NS5B polymerase inhibitor such as Sovaldi® (sofosbuvir)? ☐ **Yes** ☐ **No**
12. Is the beneficiary using viekira pak in combination with another NS5A inhibitor? ☐ **Yes** ☐ **No**
13. Is the beneficiary requesting the regimen for re-treatment and either failed to achieve a SVR (defined as a lower limit HCV RNA of 25 IU/mL) or relapsed after achieving a SVR during a prior successfully completed treatment regimen consisting of Sofosbuvir? ☐ **Yes** ☐ **No**
14. Is the beneficiary requesting the regimen for re-treatment and either failed to achieve a SVR (defined as a lower limit HCV RNA of 25 IU/mL) or relapsed after achieving a SVR during a prior successfully completed treatment regimen consisting of Ledipasvir? ☐ **Yes** ☐ **No**
15. Does the beneficiary have decompensated liver disease as defined by Child-Pugh classification score of Child Class B or C (VIEKIRA PAK™ is contraindicated in beneficiaries with moderate to severe hepatic impairment (Child-Pugh B and C)? ☐ **Yes** ☐ **No**
16. Has the beneficiary attempted a previous course of therapy with Viekira Pak? ☐ **Yes** ☐ **No**
17. Does the beneficiary have any FDA labeled contraindications to Viekira Pak? ☐ **Yes** ☐ **No**

Signature of Prescriber: _____ Date: _____

(Prescriber Signature Mandatory)

I certify that the information provided is accurate and complete to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.